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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,974	07/11/2003	Anneli Torronen	16833	4053
23389	7590	08/07/2006	EXAMINER	
SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/617,974	TORRONEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTQ-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicants amendment, filed 5-22-06, is acknowledged. Claims 1, 5, and 10 were amended.

Claims 1-17 are pending in this application.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-7, 9-15 and 17 rejected under 35 U.S.C. 102(b) as being anticipated by Bayless et al.

The claims are drawn to maintaining normal blood pressure, treating hypertension, reducing blood pressure using glycine betine.

Bayless et al. teach method of treating a condition of hypertension to a subject in need thereof by administering a combination calcium agent, methionine compound and betaine (see claim 3 of the reference). The reference states that betaine is in a concentration of .5 to 5 grams (see claim 3). Note that this concentration is within ranged claimed in claim 11-15 of the reference.

Hypertension is a common disorder in which blood pressure remains abnormally high (a reading of 140/90 mm Hg or greater). Thus treatment of hypertension would necessarily result in both reduction of high blood pressure and normalization of blood pressure. Thus, the reference meets the limitation of claims 1 and 5. Even though the reference teach the disclosure of a combination of agents, the claimed invention utilizes the claim language of comprising. The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

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Thus, the claims allow for “unrecited elements” and as such the combination disclosed in the reference anticipates the claimed invention.

3. Claims 1-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (ZA9503839) for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to maintaining normal blood pressure, treating hypertension, reducing blood pressure using glycine betine.

Applicants argue that the claims have been amended to recite the language “consisting essentially of” which specifically exclude the addition of  $MgCO_3$  in the betine hydrochloride composition. Applicants argue that the reference “requires that  $MgCO_3$  be used in the combination with the betaine, while the present invention as now claimed excludes the possible use of said composition.” Applicants state, however, that the amended claims “would allow for glycine betaine to be administered in various forms or products as indicated by the specification. . . What the amendment does accomplish is the restriction of the product to be administer from including other material ingredients such as those required by Bayless et al. [and Davis et al.]” Davis et al. Teach treating condition of hypertension by administering a combination of magnesium agent and betaine. The claimed invention as newly amended could not include the addition of Magnesium Carbonate.

Applicants arguments have been fully considered but have not been found persuasive.

First, the MPEP states “For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, ‘consisting essentially of’ will be construed as equivalent to ‘comprising.’”

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Applicants specification states:

“The final products comprising betaine as a blood pressure lowering substance in accordance with the present invention may thus include, 5 in addition to the betaine, ingredients normally used in such products, and they are prepared according to methods conventionally used in pharmaceutical industry, and food and dietary supplements industry, including beverages and functional products.” (see page 7 of the specification).

Thus, Applicants specification allows for the addition of agents are conventionally used in the pharmaceutical industry. Magnesium carbonate is conventionally used as a carrier in the pharmaceutical industry. For example, Gerbert et al. (US4404384) states “Convenient carriers for use in the compositions of the invention are e.g. magnesium carbonate, various sugars, starch, cellulose derivatives, gelatine, animal and vegetable oils, polyethylene glycols, solvents and excipients conventionally used in the pharmaceutical art.” (see col. 7, lines 14-25). Huguet et al. (US4888358) teaches For solid compositions, conventional non-toxic solid carriers include, for example, pharmaceutical grades of mannitol, lactose, starch, magnesium stearate, sodium saccharin, talcum, cellulose, glucose, sucrose, magnesium carbonate, and the like may be used (see col. 22, lines 34-39). Thus, it is conventional to use magnesium carbonate as a carrier in pharmaceutical formulations. Accordingly, the addition of magnesium carbonate does not affect the basic and novel characteristic(s) of the claimed invention. As a result,  $\text{MgCO}_3$  is not excluded as a result of the transitional phrase “consisting essentially of.”

Furthermore, the reference taught that “[I]n patients with cystathionine  $\beta$  synthetase deficiency, 6g of betaine, administered daily, was shown to decrease the level of homocysteine, reducing hypertension in the patients and the frequency of their seizures.” Thus, the reference teaches that the active agent is the betaine and not the  $\text{MgCO}_3$ . Given that the reference teaches the reduction of hypertension as a result of betaine, one can reasonably conclude that the addition of

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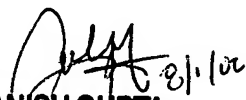
MgCO<sub>3</sub> does not affect the basic and novel characteristic(s) of the claimed invention. As a result, MgCO<sub>3</sub> is not excluded as a result of the transitional phrase "consisting essentially of."

Rejection is maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

  
**ANISH GUPTA**  
**PRIMARY EXAMINER**